Decision Memo for Pneumatic Compression Pumps for Venous Insufficiency (CAG-00075N)

Decision Summary

Our current policy covers the use of pneumatic compression pumps for patients with refractory edema from chronic venous insufficiency with significant ulceration of the lower extremities that have received standard therapy but have failed to heal after 6 months of continuous treatment. After review of all available published literature, we have found sufficient evidence to show that standard care for the treatment of chronic venous insufficiency, which results in ulceration, can be successfully treated by elevation, exercise and compression therapy. Therefore, we conclude that our current policy is appropriate and will not be changed at this time.

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Decision Memo

To: File: CAG-00075
Pneumatic Compression Devices for the treatment of generalized, refractory edema from venous insufficiency

From:

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Re: National Coverage Determination

Date: October 17, 2001

This memorandum serves four purposes: (1) outlines the description and treatment of chronic venous insufficiency (2) reviews the history of Medicare's national coverage policies for pneumatic compression pumps for the treatment of generalized refractory edema from venous insufficiency; (3) presents and analyzes the relevant clinical and scientific data related to the use of pneumatic compression pumps for venous insufficiency, and (4) delineates the rationale for our decision not to make any changes to this portion of the national coverage determination.

Clinical Background

Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins.[1] The venous system in the lower extremities is composed of a superficial venous system, a deep venous system within fascia, and a connecting perforating system. The blood flows from the superficial to the deep system through perforating veins upward toward the heart; valves impede reflux. Two major pumps propel the blood centrally: the cardiac pump and the muscle pump. During muscle contraction (systole), the muscles exert high pressure on the deep venous system and milk the blood toward the proximal veins. When muscles relax, the diastole phase, the pressure falls in the deep system and blood flows from the superficial veins to the deep veins through the communicating veins due to pressure differences. One-way valves in the veins impede an outward flow through the perforators and prevent reflux during diastole. The venous circulation is a complex system that depends on the functions of muscle, valve and veins.

CVI is distinguished from lymphedema in that lymphedema is when the lymphatic system is not able to clear fluid from the interstitial tissues of the body and return it to the bloodstream via a system of lymphatic vessels and lymph nodes.

Symptoms and signs of CVI include hyperpigmentation, statis dermatitis, chronic edema and venous ulcers. Approximately 3-11% of the adult population has skin changes and edema due to CVI. Studies of the prevalence of venous leg ulcers found that venous ulcers occur in approximately 0.18-1.3% of the adult population. Up to 40 to 50 percent of venous ulcers are caused by superficial venous insufficiency and/or perforating vein incompetence alone with normal deep vein.[2] Fewer than 10 percent of venous ulcers are due to deep venous incompetence alone. In a small number of cases, there is obstruction of the deep veins rather than valvular incompetence. Neuromuscular disorders or arthritis can affect the calf muscle pump function. These types of failures result in ambulatory venous hypertension that alters the microcirculation, causing ulceration.

There is wide consensus in the literature that compression is a necessary part of treatments for CVI and venous ulcers. Compression facilitates wound healing, reduces venous dermatitis, improves lipodermatosclerosis and counteracts venous hypertension. There are a number of methods that can be used to apply compression: elastic bandages, Unna boots, compression bandages or stockings which provide gradient pressure, compression pumps and orthotic devices. Stockings, bandages other similar systems provide static compression compared to the intermittent compression provided by pneumatic compression devices. Static compression is thought to help reduce the pressure in the veins by aiding venous return.[3]

Compression pumps consist of an inflatable boot and a pneumatic pump that fills the boot with compressed air. The boot is intermittently inflated and deflated, with cycle times and pressure that vary between devices. In addition to compression, elevation of the limb, avoidance of standing for long periods of time, and frequent ulcer cleaning and dressing changes play a major role in the treatment of CVI with venous ulcers.

There are several different types of pneumatic compression pumps. There are single chamber devices that inflate to a single pressure and there are multiple chamber devices that are individually inflated in sequential order, to produce a milking effect on the limb. Individually controlled chambers allow you to adjust the pressure over the site of an ulcer.

Leg ulcers constitute a major clinical problem among the elderly. Some leg ulcers require a long time to heal and have a high recurrence rate. Only 50% of leg ulcers heal within 4 months, 20% remain open at 2 years and 8% remain open at 5 years.[4] During the last few years there has been more interest in the pathophysiology of venous ulcers with the development of more accurate diagnostic methods and new techniques in wound care.

CVI is a lifelong condition and elastic compression stockings and other measures must be used continuously for the rest of a patient's life.

FDA Review

Pneumatic compression devices are cleared for marketing under the 510(k) process. No clinical data was necessary for clearance since they existed prior to the passage of the Medical Device Amendments of 1976.

History of Medicare Coverage of Pneumatic Compression Pumps

Medicare has covered pneumatic compression pumps for the treatment of lymphedema since 1986. In 1995 Medicare expanded coverage of pneumatic compression pumps for the treatment of venous insufficiency that results in ulceration of the lower extremity after standard wound care treatment has been tried unsuccessfully for 6 months.

Coverage Issues Manual §60-16:

The use of pneumatic compression devices may be medically appropriate only for those patients with generalized, refractory edema from venous insufficiency with lymphatic obstruction (i.e., recurrent cellulitis with secondary scarring of the lymphatic system) with significant ulceration of the lower extremity (ies) who have received repeated, standard treatment from a physician using such methods as a compression bandage system or its equivalent, but failed to heal after 6 months of continuous treatment.

Since 1995, there have been no changes in this policy.

Of note, CMS recently issued a decision memorandum on the use of pneumatic compression pumps for the treatment of lymphedema. In that decision, we clearly distinguished the 2 separate clinical conditions for use of the pneumatic compression pump, one being lymphedema and the other being chronic venous insufficiency. The previous decision memorandum on use of the pump to treat lymphedema was done in part to clarify the language in CIM 60-16, which separates the two indications and to make a clear distinction between the two indications, to be certain there is no confusion between the two policies.

Timeline of Recent Activities

April 28, 2000	CMS received a request to reconsider our current national policy on the use of pneumatic compression pumps. From that request we separated the two indications for use of the pumps and submitted this issue for a technology assessment..
November 2, 2000	CMS requested a technology assessment from the Agency of Health Research and Quality on the use of pneumatic compression pumps for the treatment of venous insufficiency and ulceration of the lower extremities.
July 14, 2001	CMS received the final Technology Assessment on use of pumps to treat chronic venous insufficiency.

Summary of Evidence

As noted earlier, an external technology assessment was requested addressing the use of the devices for chronic venous insufficiency. This assessment served as the evidence for this decision. It is available at http://www.cms.hhs.gov/coverage.

The technology assessment addressed the following questions, which are the basis of our review:

- At what point in therapy should the pneumatic compression devices be introduced?
    1. Is there evidence that pneumatic compression devices are effective in cases that have not responded to other therapy?
    2. Is there evidence that introducing pneumatic compression pumps before other therapies have been tried leads to better outcomes.
- What protocol should be used to maximize effectiveness of pneumatic compression devices?
    1. What other treatment modalities (and with what amount of supervision) must be employed along with the pump in order to maximize therapeutic benefits?
    2. Is it necessary to use elastic compression garments along with pneumatic compression devices to achieve effectiveness?
    3. Are there useful guidelines as to the duration of individual pump sessions, duration and frequency of a therapeutic course of pneumatic compression therapy?
- Are there absolute indications or contraindications to use of pneumatic compression therapy?

A systematic review of the literature on the use of pneumatic compression pumps in the home setting found eight studies that included relevant health outcomes while using the pump. The following is the inclusion criteria used to determine appropriate articles to use for this study:

- Treatment with intermittent pneumatic compression devices are a major therapy (not adjunct to surgery)
- Medical conditions Venous insufficiency of the lower extremity
  Leg Ulcer
- Compression pump in the home setting
- Health outcomes, reduction of edema or ulcer healing rate

Most patients in the studies of ulcer healing had chronic ulcers that had not healed for several months. Margolis et al.[5] studied factors that predict which venous leg ulcers will not heal with limb compression bandages alone. They found that most ulcers that were <6 months old and were <5 cm squared healed within 24 weeks with compression bandages alone. Phillips et al also found that ulcers of short duration are likely to heal with compression using a bandage or wrap alone. Essentially, the majority of studies demonstrated that these devices should be used after simple, conservative therapies have failed.

Based on analysis of these studies, the assessment concluded:

- Compression therapy is an important part of treatment for chronic venous insufficiency and venous leg ulcers.
- Long-term use of pneumatic compression devices in the home environment may be an alternative to other compression therapies for patients who are unable or refuse to comply with other methods.
- Pneumatic compression may be effective for patients who have previously failed treatment with other compression devices.
- Trials of pneumatic compression devices to treat chronic venous insufficiency and ulceration included few patients and may not have enough power to detect differences
- Study results are mixed and varied.
- Several studies showed significant improvement of long-standing chronic ulcers with the use of pneumatic compression devices that had not healed using other methods.

The Phillips et al. [6] study reanalyzed data from an Randomized Controlled Trial (RCT) of a placebo vs. oral medication taken in conjunction with compression methods. A high percentage (55%) of large chronic venous ulcers (mean duration of 27 months with mean area of 15.9 cm(2) healed in this study. However, it is hard to tell how much of the success of this study was due to a clearly defined system of wound care that included once weekly office visits with a strict protocol for ulcer treatment including specifications of dressings or the compression or a combination of both treatments.

Rowland[7] was a crossover RCT; patients were switched between the two groups after the alternative therapy was tried for several months. This was a small study of 16 patients, five of which withdrew early in the study. The mean age of patients was 69 years old. The average ulcer duration was 24 - 34 months. One group was treated with a single chamber compression pump for 1 hour each morning and evening while the other group was treated with high stretch bandaging. The patient was examined to see differences between the length of time to heal and changes in size and limb volume. Both therapies produced significant decreases with time. Although, patients reported the pump was more comfortable to use, only 3 patients were completely healed by the end of the study. The author concluded that the power of the study might be too low to detect a real difference.

Schuler et al.[8] compared the outcome difference between the use of the Unna boot and the use of sequential compression pumps. Fifty-four patients were enrolled in this trial ranging in age from 31-85. Patients using the pump were instructed to use it for 1 hour in the morning and 2 hours in the evening with their leg elevated. This group also wore stockings between pumping sessions. At the end of the six-month trial, there was no significant difference between the two groups of patients that have achieved complete healing, or a significant difference in the average healing rates.

Smith et al. [9] studied the effect of compression devices compared to those using compression stockings alone. This study included 45 patients ranging in age from 42-78. One out of 24 patients healed within 3 months in the controlled group (2.1% of ulcer area per week) compared to ten out of 22 patients (19.8% of ulcer area per week) that healed using the pump. This was an intention to treat analysis. Both groups received standard wound care, wore compression stockings and were told to elevate legs when sitting. Any and all of these treatments may be responsible for improvement.

Mulder et al. [10] is a historical control study of 10 patients, studied the effect of pneumatic compression devices. Patients were their own control. After using the Unna boot for 42 days, patients were instructed to use sequential compression devices. Two patients dropped out of the study, one for equipment failure and one for lack of compliance. There was a significant decrease in wound area over time with only one patient that completely healed in 120 days.

CMS Analysis

In determining whether any revisions should be made to the present policy, our analysis was based on the questions addressed in the technology assessment

At what point in therapy should pneumatic compression devices be introduced?

Several studies showed an improvement in signs and symptoms of chronic venous insufficiency with use of pumps. Although there are different timeframes, in general most studies did not use the device until six months have elapsed. There was insufficient and conflicting evidence on the effectiveness of the introduction of pneumatic compression pump therapy when a person has not responded to other therapies. There were multiple studies which showed that standard care, elevation, exercise and compression is an effective therapy and does lead to prevention of ulcers and improvements in the underlying condition. Therefore, we will not change our six-month minimum requirement.

What protocol should be used to maximize effectiveness of the pneumatic compression devices?

As the technology assessment points out, the studies in this area are mixed, and are of relatively poor quality. In some studies, the devices were used in combination with other therapies; in other studies, they were used as sole treatment. It cannot be clearly determined as to the precise protocol. At a minimum, however, simple conservative therapies such as wraps, bandages, and elevation need to be tried.

Are there absolute indications or contraindications to use of pneumatic compression therapy?

In general, reporting of adverse events is poor in most areas of medical research. Few adverse events have been noted with the use of these devices. However, adverse events have been cited regarding the use of the pump to prevent and treat deep vein thrombosis.[11] These events may be considered relative rather than absolute indications. Peroneal neuropathy and compartment syndrome, where circulation and function of tissues within a closed space are compromised by increased pressure leaving muscles and nerves susceptible to injury has been reported from pump use. Another associated risk of the use of the pumps to treat venous insufficiency is genital edema.[12]

There are few relative contraindications for the use of the pump; they include serious arterial insufficiency, edema due to congestive heart failure, active phlebitis, deep vein thrombosis or the presence of localized wound infection or cellulitis.

Conclusion

Our current policy covers the use of pneumatic compression pumps for patients with refractory edema from chronic venous insufficiency with significant ulceration of the lower extremities that have received standard therapy but have failed to heal after 6 months of continuous treatment. After review of all available published literature, we have found sufficient evidence to show that standard care for the treatment of chronic venous insufficiency, which results in ulceration, can be successfully treated by elevation, exercise and compression therapy. Therefore, we conclude that our current policy is appropriate and will not be changed at this time.

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1 Nicolaides, A.N., Investigation of Chronic Venous Insufficiency: A consensus statement (France, March 5-9, 1997). *Circulation*, 2000. 102(20):p.E126-63

2 Nelzen O, Bergqvist D, Lindhagen A., Long term prognosis for patients with chronic leg ulcers: A prospective cohort study. *Eut J Vasc Endovasc Surg,* 1997;13(5):500-8

3 Nelson, E., S. Bell-Syer, and N. Cullum, *Compression for preventing recurrence of venous ulcers,* The Cochrane Library; Oxford: Update Software, 2001.

4 *Consensus paper on venous leg ulcer. The Alexander House Group.* J Dermatol Surg Oncol, 1992. 18(7): p592-602.

5 Margolis, D.J., J.A. Berlin, and B.L. Strom, *Which venous leg ulcers will heal with limb compression bandages?* Am J Med, 2000. 109(1):p. 15-9.

6 Phillips et al, *Prognostic indicators in venous ulcers,* J Am Acad Dermatol, 2000. 43(4):p.627-30.

7 Rowland, J., *Intermittent pump versus compression bandages in the treatment of venous leg ulcers.* Australian and New Zealand journal of surgery, 2000. 70(2):p.110-113.

8 Schuler, J.J., et al., *Treatment of chronic venous ulcers using sequential gradient intermittent pneumatic compression.* Phlebology, 1996. 11(3) p.111-116.

9 Smith, P.C., et al., *Sequential gradient pneumatic compression enhances venous ulcer healing: a randomized trial.* Surgery, 1990. 108(5): p.871-5.

10 Mulder, G.D. and T.M. Reis, *Venous ulcers:pathophysiology and medical therapy.* American family physician, 1990.42(5):p.1323-30.

11 Lachmann, E.A., et al. *Complications associated with intermittent pneumatic compression.* Arch Phys Med Rehabil, 1992. 73(5):p 482-5.

12 Boris M, Weindorg S, Lasinski BB, *The Risk of Genital Edema After External Pump Compression for Lower Limb Lymphedema,* Lymphology, 1998.

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